

Notice of Allowability

Application No.

09/759,112

Examiner

Zachariah Lucas

Applicant(s)

MULLER ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response of December 29, 2003.
2. ☒ The allowed claim(s) is/are 1,10-12,14,15 and 19-21.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 3-4-2004.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

Status of the Claims

1. In the prior action, mailed on September 25, 2003, claims 1-20 were pending in the application, with claim 16-20 withdrawn as to non-elected inventions, and claims 1-15 rejected. In the Response, filed on December 29, 2003, the Applicant cancelled claims 4, 5, and 7-9; amended claims 1 and 12; and added new claim 21.
2. In the present Examiner's Amendment, claims 2, 3, 6, 13, and 16-18 are cancelled, and previously withdrawn claims 19 and 20 are rejoined with claims 1, 10-12, 14, 15, and 21.
3. Claims 1, 10-12, 14, 15, and 19-21 are allowed.
4. Claims 1, 10-12, 14, 15, and 21 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 19 and 20, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 19 and 20 hereby rejoined and fully examined for patentability under 37 CFR 1.104.
5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Meadows on March 4, 2004.

The application has been amended as follows:

Claims 2, 3, 6, and 13 are cancelled from the application as being indefinite for failing to further limit the claims from which they depend.

Claims 16-18 are cancelled as drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

6. **(Prior Rejection-Withdrawn)** The term "substantially identical" in claims 4 and 7 is a relative term which rendered the claims indefinite. In view of the cancellation of these claims, the rejection is withdrawn.
7. **(Prior Rejection-Withdrawn)** Claims 1, 11, 14, and 15 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims described a genus of polynucleotides encoding any anti-idiotypic antibody that binds to a human or primate anti-HIV antibody. In view of the amendment of the claims such that the claims more narrowly define a structure associated with the claimed function, the rejection is withdrawn.
8. **(Prior Rejection-Withdrawn)** Claims 1-8, 11-15 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding the sequences of SEQ ID NO: 5 or 24, does not reasonably provide enablement for polynucleotides encoding only the sequence of fragments of the complete variable regions lacking one or more of the CDRs, or encoding variable regions of antibodies other than 1F7 that can bind anti-HIV

antibodies. The claims were rejected on three grounds. First, the Applicant has not provided an enabling disclosure for any polynucleotide sequence encoding a variable region of any antibody other than the 1F7 antibody. Second, the Applicant is not enabled for polynucleotides that encode either all of the FR and CDR regions of the antibody in an order other than that disclosed in SEQ ID NOs: 7 and 24. Third, the Applicant is not enabled for polynucleotides that encode only FR sequences from the anti-idotypic antibodies. In view of the amendments to the claims, the rejection is withdrawn.

9. **(Prior Rejection-Withdrawn)** Claims 4 and 7 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides comprising at least one of the claimed CDR sequences, does not reasonably provide enablement for polynucleotides encoding polypeptides substantially identical to those sequences. In view of the cancellation of these claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

10. **(Prior Rejections-Withdrawn)** Claims 1-8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes et al., U.S. Patent 5,928,904. Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Lohman et al., Gene 105: 283-84). These claims read on polynucleotides encoding the CDRs represented by the polypeptides of claim 4, or polynucleotides encoding at least one CDR or FR of the antibody 1F7. In view of the amendment to the claims limiting the claimed inventions to those encoding either SEQ ID NO: 7 or 24, the rejections are withdrawn.

Claim Rejections - 35 USC § 103

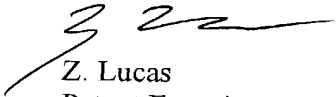
11. **(Prior Rejection-Withdrawn)** Claims 12, 14, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Homes et al. in view of Black. In view of the amendments to the claims requiring that the sequences code for either SEQ ID NO: 7, or SEQ ID NO: 24, the rejection is withdrawn.


Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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3/8/04